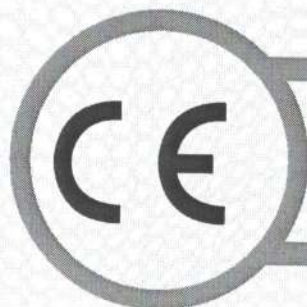




DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019 Type IIR

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-DY-01-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Guangzhou Dayun Medical Technology Co., Ltd.

Address: No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guangdong, China

Product Information

Name: Disposable Medical Mask (Non-Sterile)

Model: DY-01 (17.5cm × 9.5cm), DY-02 (14.0cm × 9.0cm), DY-03 (12.0cm × 7.0cm), TGL-03 (17.5 × 9.5cm)

GMDN: 35177

Basic UDI- DI: 697308854mask0122



Classification: Class I Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Name: Feng Jian

Signature:

Date: 5th of Feb 2021

Position: General Manager **Place:** Guangzhou / China



中国认可
国际互认
检测
TESTING
CNAS L0412

检测报告

(Test Report)

No. GOLL5F8P189175L1

样品名称
(Sample Description)

一次性使用医用口罩（非灭菌）
Disposable medical mask (Non-sterile)

委托单位
(Applicant)

广州达运医疗科技有限公司
Guangzhou Dayun Medical Technology Co.,Ltd.

声明 Statement

1. 本报告无检验检测专用章、报告骑缝章和批准人签章无效。
This report is invalid without special seal of inspection, cross-page seal and the approver's signatures.
2. 本报告页面所使用“PONY”、“谱尼”字样为本单位的注册商标,其受《中华人民共和国商标法》保护,任何未经本单位授权的擅自使用和仿冒、伪造、变造“PONY”、“谱尼”商标均为违法侵权行为,本单位将依法追究其法律责任。
The pattern and characters of "PONY" and "谱尼" used in this report are protected by the trademark law of the People's Republic of China. Any unauthorized usage, counterfeit, forgery and alteration of trademarks of "PONY" and "谱尼" are the violations of the law. The PONY has the right to pursue all legal liabilities of the subject of the delict.
3. 委托单位对报告数据如有异议,请于报告完成之日起十五日内(初级农产品报告请于报告收到之日起五日内)向本单位书面提出复测申请,同时附上报告原件并预付复测费。
If the applicant has any questions about the results, shall provide a written retest application with the original report, and prepay the retest fees to PONY within fifteen days since the approval date (as an exception, it shall be within five days since the date received for the primary agriculture products report).
4. 委托单位办理完毕以上手续后,本单位会尽快安排复测。如果复测结果与异议内容相符,本单位将退还委托单位的复测费。
After the applicant finishes the procedure mentioned above, PONY shall arrange the retest as soon as possible. If the retest result accords with the applicant dissent, PONY shall refund the retest fees.
5. 不可重复性或不能进行复测的实验,不进行复测,委托单位放弃异议权利。
Tests that can not be repeated and tested shall not be carried out again.
6. 委托单位对样品的代表性和资料的真实性负责,否则本单位不承担任何相关责任。
The applicant should undertake the responsibility for the provided samples' representativeness and document authenticity. Otherwise, PONY has not any relevant responsibilities.
7. 本报告仅对所测样品负责,报告数据仅反映对所测样品的评价,对于报告及所载内容的使用,使用所产生的直接或间接损失及一切法律后果,本单位不承担任何经济和法律后果。
This report is only responsible for the provided sample. The test results only represent the evaluation of the tested sample. PONY will not be responsible for any economical or legal liability generated from direct or indirect usage of the test report.
8. 本单位有权在完成报告后按规定方式处理所测样品。
PONY has the right to dispose the tested sample by rules, after approval of the test report.
9. 本单位保证工作的客观公正性,对委托单位的商业信息、技术文件等商业秘密履行保密义务。
PONY assures objectivity and impartiality of the test, and fulfills the obligation of confidentiality for applicant's commercial information, and technique document.
10. 本报告私自转让、盗用、冒用、涂改,未经本单位批准的复制(全文复制除外)或以其它任何形式的篡改均属无效,本单位将对上述行为追究其相应的法律责任。
The report is invalid in case of illegal transfer, embezzlement, imposture, modification or any altering, reproducing except in full, without approval of PONY. PONY shall investigate and affix the applicant's legal liability accordingly.

▲ 防伪说明 (Anti-counterfeiting Description):

- (1) 报告编号是唯一的;
The test report has exclusive report code.
- (2) 报告采用特制防伪纸张印制,纸张表面带有"PONY"防伪纹路,该防伪纹路不支持复印,即复制件不会带有"PONY"防伪纹路。
The test report is printed by anti-copying paper whose surface shows "PONY" security print with specific anticounterfeiting technique. Security print will disappear after copying. Duplicates are not expected to give "PONY" security print under any circumstances.



全国服务热线
400-819-5688

WWW.PONYTEST.COM

扫描二维码
关注谱尼测试微信



公众号 PONY4008195688

北京实验室: (010) 83055000	武汉实验室: (027) 83997127	哈尔滨实验室: (0451) 58627755
上海实验室: (021) 64851999	长春实验室: (0431) 85150908	石家庄实验室: (0311) 85376660
青岛实验室: (0532) 88706866	大连实验室: (0411) 87336618	乌鲁木齐实验室: (0991) 6684186
深圳实验室: (0755) 26050909	郑州实验室: (0371) 69350670	呼和浩特实验室: (0471) 3450025
天津实验室: (022) 23607888	西安实验室: (029) 89608785	杭州实验室: (0571) 85806807
苏州实验室: (0512) 62997900	太原实验室: (0351) 7555762	宁波实验室: (0574) 87977185
		温州实验室: (0577) 88271060
		合肥实验室: (0551) 63843474
		广州实验室: (020) 89224310
		厦门实验室: (0592) 5568048
		成都实验室: (028) 87702708

检测结果 (Test Results)

No. GOLL5F8P189175L1

第 1 页, 共 3 页 (page 1 of 3)

样品名称 (Sample Description)	一次性使用医用口罩 (非灭菌) Disposable medical mask (Non-sterile)	样品规格 (Sample Specification)	14.5cm *9.5cm
委托单位 (Applicant)	广州达运医疗科技有限公司 Guangzhou Dayun Medical Technology Co.,Ltd.	商标 (Trade Mark)	—
到样日期 (Received Date)	2020-10-09	生产日期或批号 (Manufacturing Date or Lot No.)	20201008 20201008
检测日期 (Test Date)	2020-10-09~2020-10-20	样品等级 (Sample Grade)	—
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩颗粒物过滤效率及气流阻力测试仪 等 Respirator particle filtration efficiency and airflow resistance tester etc.		
备注 (Note)	1.型号: DY-02 Model: DY-02 2.生产单位/受检单位: 广州达运医疗科技有限公司 Manufacturer/Tested company: Guangzhou Dayun Medical Technology Co.,Ltd. 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant. 5.限值标准: BS EN 14683:2019 (IIR 型) Limit Standard: BS EN 14683:2019(Type IIR)		
	编制人 (Edited by)	张娜	
	审核人 (Checked by)	张慧珍	
	批准人 (Approved by)	孙兆增	
	签发日期 (Issued Date)	2020 年 10 月 20 日	

检测结果 (Test Results)

No. GOLL5F8P189175L1

第 2 页, 共 3 页 (page 2 of 3)

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)			单项结论 (Evaluation)	检测方法 (Test Method)
1	细菌过滤效率 (BFE) Bacterial filtration efficiency(BFE)	%	≥98	99.91			符合 Pass	BS EN 14683:2019 附录 B Appendix B
				99.76				
				99.91				
				99.95				
				99.72				
2	压力差 Differential pressure	Pa/cm ²	<60	A	B	C	符合 Pass	BS EN 14683:2019 附录 C Appendix C
				1-1	22.2	21.8		
				1-2	22.3			
				1-3	23.4			
				1-4	20.2			
				1-5	21.1			
				2-1	27.1	25.6		
				2-2	20.9			
				2-3	21.9			
				2-4	25.7			
				2-5	32.2			
				3-1	25.0	22.0		
				3-2	14.8			
				3-3	17.5			
				3-4	23.2			
				3-5	29.4			
				4-1	23.7	21.8		
				4-2	24.5			
				4-3	21.3			
				4-4	16.8			
				4-5	22.9			
				5-1	22.4	21.3		
				5-2	22.2			
				5-3	22.1			
				5-4	21.7			
				5-5	17.9			

检测结果 (Test Results)

No. GOLL5F8P189175L1

第 3 页, 共 3 页 (page 3 of 3)

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)	单项结论 (Evaluation)	检测方法 (Test Method)
3	抗溅压力 Splash resistance pressure	kPa	≥ 16.0	32 个试样均 > 16.0 Splash resistance pressure of 32 samples were all greater than 16.0	符合 Pass	ISO 22609:2004
4	微生物洁净度 Microbial cleanliness	cfu/g	≤ 30	20	符合 Pass	BS EN 14683:2019 附录 D Appendix D
				21		
				13		
				16		
				20		

备注 Note: A-试样编号-测试区域编号 Test Specimen number-Test area number; B-每个测试区域的压力差 Differential pressure for each test area; C-每个试样的平均压差 The averaged differential pressure for each test specimen.

照片 Photo:



以下空白
(End of Report)